EXHIBIT 4

to

PAUL D. BRACHMAN DECLARATION IN SUPPORT OF INTUITIVE'S MOTION FOR LIMITED SUPPLEMENTAL DISCOVERY

UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

IN RE: DA VINCI SURGICAL ROBOT ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL CASES	Lead Case No. 3:21-cv-03825-VC Judge: The Honorable Vince Chhabria
SURGICAL INSTRUMENT SERVICE COMPANY, INC., Plaintiff/Counterclaim-Defendant vs. INTUITIVE SURGICAL, INC., Defendant/Counterclaimant.	Case No. 3:21-cv-03496-VC Judge: The Honorable Vince Chhabria

DECLARATION OF DAVID ROSA

I, David Rosa, declare as follows:

1. I am Executive Vice President and Chief Strategy and Growth Officer at Intuitive Surgical, Inc. ("Intuitive"). In that role, I am responsible for identifying pathways for growing the company and help craft our strategy for doing so. I report directly to Intuitive's CEO, Gary Guthart. I have personal knowledge of the facts set forth herein, and if called to testify, I could and would testify competently thereto.

2. I joined Intuitive in March of 1996 (the year after it was founded) as employee number nine. I have been at the company for all 27 years since then. I am the second-longest tenured employee.

3. Through my various roles over the years, I have had deep involvement in essentially every aspect of the company's business, including product design, marketing, sales, regulatory compliance, and overall strategy.

4. When I joined Intuitive in 1996, I started as a mechanical engineer helping design the da Vinci setup joints and surgeon console. Shortly thereafter, I became a clinical applications engineer. That role involved working closely with healthcare teams, both teaching them how to use our products and incorporating their feedback into our design process. In that role, I "scrubbed in" to dozens of early da Vinci surgeries. After that, I held several roles involving product development and marketing to hospital customers, progressing upward in seniority. I became the leader of the product quality and regulatory team in 2011. In that role, I had overall responsibility for Intuitive's compliance with FDA requirements. I was promoted to Chief Scientific Officer (which included my previous regulatory oversight responsibilities) in 2014 and to Chief Commercial Officer (which involved leadership of the sales and marketing organizations for the company) in 2015. I was promoted to my current role in 2022.

5. I have a B.S. in mechanical engineering from California Polytechnic University and an M.S. in mechanical engineering from Stanford. I have developed several patented technologies related to the da Vinci system.

I. The Da Vinci

6. I was involved in the early development of the da Vinci Surgical System.

7. Intuitive was founded to try to meet an unmet surgical need. The benefits of minimally invasive surgery versus open surgery were well established. However, adoption of minimally invasive surgery (laparoscopy) had stalled because it was too difficult for many surgeons to perform more complex procedures. Intuitive wanted to find a way for all surgeons to use minimally invasive surgical techniques. If Intuitive could enable more widespread use of minimally invasive surgery, more patients could benefit from the improved outcomes. Intuitive aimed to address the limitations of existing laparoscopic equipment, including non-intuitive instrument movement, limited degrees of freedom, poor sensory feedback, and two-dimensional visualization.

8. The first da Vinci systems were introduced commercially in the United States in 2000, following years of innovation, exhaustive testing, and detailed review by the United States Food & Drug Administration ("FDA"), which classifies a da Vinci system and the instruments used with it as Class II medical devices that require FDA "510(k)" clearance before they can be marketed and used on patients.

9. Intuitive's da Vinci systems are often referred to as "robotic" surgical systems, as they allow a surgeon to operate sitting at a console that permits the surgeon to control "EndoWrist" surgical instruments that are attached to mechanical arms suspended above the patient. EndoWrists are inserted into the patient through small incisions and can perform extremely precise, fine-tuned movements (cutting, grasping, suturing, etc.), allowing surgery to be done in a "minimally invasive" manner. The surgeon views the activity at the console through a three dimensional video feed from an endoscope mounted on one of the arms of the system and inserted into the body along with the EndoWrists. Da Vinci systems allow surgeons to perform procedures with significantly reduced trauma to the patient when compared with open surgery, fewer conversions to open surgery when compared to traditional laparoscopic surgery and improved patient outcomes, including fewer complications and faster recovery times, when compared with both.

10. Intuitive's "The da Vinci Si System Overview" video at https://www.youtube.com/watch?v=0VGgDT-IzFs provides a good overview of the da Vinci Si System's components and how they function.

11. Like many innovative products, da Vinci systems have evolved over time, and Intuitive has introduced new models from time to time, with support eventually being phased out for outdated models. The Si systems were introduced in the United States in 2009; Intuitive ceased selling new Si systems in the United States in 2018 and we expect to cease support for those systems, including the sale of new S/Si EndoWrists, in the United States by the end of 2024. The models that are primarily used today in the United States are the Xi, introduced in 2014, and the X, introduced in 2017. The X and Xi systems use the Generation 4 collection of EndoWrist instruments; the S and Si systems use Generation 3 S/Si EndoWrists, which reflect older designs.

12. Intuitive possesses numerous unexpired patents on innovations embodied in da Vinci S, Si, X, and Xi systems and the EndoWrists used with those systems.

II. Intuitive's Sales to Hospitals

13. As noted above, I have extensive experience working with our hospital customers, and have held leadership roles in Intuitive's sales and marketing organizations for a number of years.

14. The hospitals and surgery centers that purchase da Vinci systems are highly sophisticated consumers. A sale of a da Vinci is routinely preceded by extensive presentations on the costs and benefits to the hospital of having a da Vinci available as an alternative modality for performing many types of surgery. The cost analysis includes ongoing costs for EndoWrists and accessories used with the system.

15. To compete, Intuitive must establish that clinical outcomes and other measures are consistently better with da Vinci surgery when comparing with traditional laparoscopic and open surgery options. As a result, the total cost to treat a patient with da Vinci surgery is often less than the cost of traditional laparoscopic or open surgery.

16. Intuitive has done extensive research to demonstrate cost savings across a patient's episode of care, showing that the up-front cost of equipment alone does not account for the total costs of treating a patient across different surgical modalities.

17. **Exhibit 1** to my declaration is a presentation typical of those we make to hospitals (Business Alignment Meeting deck, Intuitive-00001237). The entire presentation is oriented around comparisons across robotic, traditional laparoscopic, and open surgery.

18. For example, Slides 8–9 show increasing shares of da Vinci surgeries for several common procedures, with decreasing shares of open surgery.

19. As another example, the "Comparative Outcomes" section (starting at slide 29) walks through peer-reviewed studies showing how da Vinci surgery stacks up better on many dimensions, including total operating room time, risk of complications, and reduced recovery time.

20. Our customer-facing cost analysis includes ongoing costs for EndoWrists and accessories used with the system. Customers are fully aware when they purchase a da Vinci that its EndoWrists are limited use devices that will require replacement after a fixed number of uses.

21. If our sales effort is successful, each purchaser or lessor of a da Vinci enters into a contract with Intuitive, typically in the form of a Sales, Licensing and Service Agreement ("SLSA") or corresponding lease agreement with Intuitive. The terms of those contracts are heavily negotiated.

III. EndoWrists

22. I am very familiar with the design of EndoWrists, the risks of EndoWrist failure, and the various ways Intuitive seeks to mitigate those risks. I was involved in early development of the da Vinci System, and had a particular responsibility for safety issues during my time as head of the regulatory department. From the early days of Intuitive, our current and prospective customers wanted to know about the useful life of EndoWrists.

23. Intuitive has obtained 510(k) clearances for all EndoWrists used with da Vinci systems. That FDA clearance, and the resulting labeling of the devices, reflect use restrictions developed through extensive testing, and this is reviewed by FDA for reasonable assurance of safety and effectiveness. Intuitive adopted the use restrictions at a time when we were a new company struggling to convince customers to accept a brand-new technology.

A. EndoWrist Design

24. One of the primary innovations of the da Vinci is the unique design of EndoWrists, which mimic and even exceed the range of motion of the human wrist, allowing the surgeon to move an instrument easily inside the body to the desired angles with great precision. This feature requires use of fine wire cables that thread through a complex pulley system. This design gives the surgeon tremendous flexibility, but at the cost of making the instruments vulnerable to wear and tear. This is in contrast to traditional laparoscopic instruments that are push rod driven and do not have a pulley system.

25. The vast majority of EndoWrist instruments are 8mm in diameter. This measurement is important because an incision of this size or smaller is unlikely to need special suturing to prevent a hernia. Generally, if the incision is larger than 10 millimeters, the incision will need to be closed at the end of surgery to prevent a hernia. And of course, in general, a larger incision generally means a longer and more painful recovery for the patient. Unlike other types of cable and pulley systems that are much larger (and thus can be designed with large margins of safety and very long life (*e.g.*, elevators)), the size requirements of EndoWrists result in much tighter bending radii for the cables than typical for cable-pulley drive mechanisms. In addition, because EndoWrists have multiple joints, the cables are arranged such that they bend in both directions, over a very small distance, and in some cases, in non-ideal cable fleet angle conditions, thus further exacerbating cable wear.

26. All of these factors increase cable fatigue, which would tend to lead first to individual cable strand breakage, then cable bundle breakage, thereby reducing the cross-section of the overall cable and increasing the load on the remaining cables, and ultimately leading to complete cable breakage.

27. In addition to the factors listed above, EndoWrists are subjected to cleaning and sterilization cycles prior to each use. These cycles can impart significant thermal and chemical stresses on EndoWrists, and in particular, on the fine wire cables. Given all of this, and unlike traditional laparoscopic surgical instruments, EndoWrists must be designed with limited uses as EndoWrists can fail after only a modest number of uses and cleaning and sterilization cycles. Failure can occur in multiple ways, including (among others), metal fatigue of the fine wire cables or increased friction

within the intricate pulley system, that can lead to a degradation of performance over time or sudden failure of the instrument to maintain the needed precision of movement. Although failures are rare, the result of such failures mid-surgery can range from modest (e.g., requiring the instrument to be withdrawn from the body and replaced) to serious (if, for example, tiny pieces of the instrument fall into the body) to catastrophic (if, for example, the wrist feature fails and leads to unexpected or unwanted motion just as the surgeon is performing a task adjacent to a major blood vessel).

B. EndoWrist Risk Management, Life Testing, and Use Limits

28. Because of the potential implications of an EndoWrist failure, the useful life of EndoWrists has long – going back more than 20 years – been a focus of exhaustive testing programs, which formed the foundation for the required safety demonstrations to FDA. Life testing is just one part of Intuitive's overall design control process. Design control is a systematic framework used to demonstrate that a product meets the needs of the end-user (intended use) while maintaining safety and effectiveness. Design control involves: (i) design verification, which considers and tests the engineering of a product, and (ii) design validation, which considers whether the product meets the needs of the end-user. Through these processes, Intuitive engineers comprehensively ensure each device meets every end-user and engineering requirement identified in the design input documents. Every single specification must be met through testing and verification. For EndoWrists, we must have sufficient statistical certainty that the device will perform just as well on the last use as the first.

29. The determination that use limits would be set, the ranges in which they would fall, and the accompanying fundamental design choices for the first generation of EndoWrists, were made more than two decades ago. It was clear from the beginning that use limits would be necessary to give EndoWrists a reasonable margin of safety. The nature and extent of those limits required evaluation of the wear and tear the instruments would be expected to experience, not just in typical surgical procedures, but also in the added stresses associated with the rigorous cleaning and sterilization processes required for each use. Over a period of years, Intuitive performed extensive testing on EndoWrists to evaluate the number of uses that could be tolerated without exceeding statistical targets

for failure. These targets were determined based on a frequently used statistical methodology known as a Weibull Distribution analysis.

30. Intuitive's life testing is a verification activity performed to evaluate the reliability of instruments. The results of the testing are used as a primary resource for justifying the maximum number of uses for each instrument. Life testing requires instruments to be used for surgical tasks per individually crafted simulated surgical use work instructions. Simulated surgical use instructions are developed by the Clinical Development Engineering team. The surgical tasks of the simulated surgical use are designed to represent actual maneuvers performed and forces encountered during minimally invasive surgical operations. The number of repetitions to be completed within a simulated surgical use is determined by conservatively estimating the number of such maneuvers performed during an applicable surgical operation. The instrument also undergoes a number of cleaning and sterilization cycles during life testing as it would when used by a customer.

31. The data resulting from Intuitive's life testing and other risk management activities, along with the use limits generated based on the data, were submitted to FDA in Intuitive's 510(k) applications, with the use limits identified as prerequisites for the regulatory clearance that was sought and granted. EndoWrist instruments were explicitly described to, and cleared by, FDA as "limited use" instruments containing use counters that cause each EndoWrist to cease functioning after its final approved use. For most S/Si instruments, Intuitive proposed, and FDA cleared, a limit of 10 uses.

32. Intuitive's marketing group (and in particular the clinical marketing subgroup that promoted efforts to tailor our products to customer needs) provided input on the use limits to be selected. The primary content of that input, particularly in the early days, was strong encouragement to redesign EndoWrists under development to allow more uses than early testing supported.

C. X/Xi Extended Use EndoWrists

33. Historically, most S/Si EndoWrists were labeled for 10 uses, as supported by life testing performed by Intuitive and submitted to regulatory agencies before the instruments were marketed and sold. Over the years, a number of incremental product improvements, including material and design changes, were made to many X/Xi instruments after their initial introduction. Because of these

improvements and lower rates of returned instruments (known as "RMAs," discussed below), Intuitive tested a hypothesis that certain da Vinci X and Xi instruments could withstand additional uses. The number of uses that our new testing showed could be supported for these improved instruments ranged as high as 18, although most were below 18; no da Vinci X/Xi instruments were validated as being safe to use for more than 18 lives.

34. To be clear, the "extension" of use limits Intuitive pursued through its Extended Use program was an increase in the number of uses for which certain X/Xi EndoWrists were originally programmed and labeled, based on testing that verified and validated those additional uses following product improvements. It did not involve modification of expired instruments. Following what Intuitive understood to be the applicable FDA requirements for this change for Intuitive as the original manufacturer, Intuitive initially relied on "non-filing justifications" for the "extended" use limits, but after the FDA made it clear to Intuitive that we required new 510(k) clearances for the additional uses, Intuitive sought and obtained FDA clearance for all of the X/Xi instruments with increased uses. These extended use limits were made possible by years of incremental product improvements. Many of these improvements were not applied to the S/Si instruments and therefore those instruments still have a lower number of verified and validated lives when compared to their X/Xi counterpart instruments.

35. The goal of the Extended Use program was to increase customer value while still preserving safe and adequate performance throughout the instrument lifetime, with no impacts to Intuitive's risk-based confidence and reliability requirements.

D. The Use Counter

36. Each EndoWrist has a computer chip that tracks critical information about the instrument, including the maximum number of uses, the number of surgeries for which it has been used, and calibration data for control of the instrument. The chip is programmed to render the instrument nonfunctional after the maximum allowed number of uses is reached. This prevents a user from inadvertently (or otherwise) exceeding the number of cleared uses for the instrument.

37. The computer chip used for this purpose in S/Si EndoWrists is called the "Dallas" chip and uses small spring-loaded pins to communicate with the da Vinci system when the EndoWrist is

attached. For X/Xi systems, Intuitive upgraded to a wireless connection for the communication of the instrument, calibration, and use count information between the EndoWrist and the rest of the system to improve consistency in the communication channel; this required the chip to be encrypted for security purposes to avoid remote tampering or other types of wireless attacks.

E. Intuitive's Consideration of a Possible Refurbishment Program

38. From 2016 to 2020, Intuitive pursued a project to see if we could refurbish used X/Xi instruments at a lower cost than new instruments. Intuitive's program contemplated full refurbishment of X/Xi instruments, including replacing the cables and other sensitive parts that were prone to failure after multiple uses.

39. Intuitive abandoned the program because, after extensive analysis, we determined that the cost of proper refurbishment for most X/XI EndoWrists exceeded the cost of making new instruments, making the program commercially infeasible.

IV. Returned Materials Authorization and Discovery of EndoWrist Tampering

40. Although it is the full intention of Intuitive to release products that are durable enough to withstand expected abuse throughout their entire lifetime, failure modes resulting from customer behaviors or other factors can be difficult to predict. Following launch, as more customers use a product, some failure modes are seen at higher frequencies than others, and are reported to Intuitive through Return Material Authorizations (RMAs) and the complaint management system. Intuitive maintains these RMA and complaint management systems as part of its commitment to quality and regulatory obligations. The RMA system provides liberal "no questions asked" warranty coverage for EndoWrists that experience malfunction for almost any reason other than clear and unmistakable abuse. Returned devices are carefully evaluated to assess and track the causes of any failures.

41. Intuitive first became aware of third parties modifying Si EndoWrists through returns of EndoWrists to Intuitive through the RMA process. An Intuitive team that is responsible for failure analysis of returned products disassembled some of the returned instruments and discovered that they had been modified with the insertion of what Intuitive later learned were Rebotix Interceptor chips.

42. Intuitive began to reach out to customers who were using remanufactured EndoWrists, explaining that the use limits are grounded in extensive safety and performance testing, and that resetting the use counters could create safety concerns for patients. Intuitive expressed the view that such modifications required FDA clearance.

43. If the customer continued to use remanufactured EndoWrists, Intuitive would send the customer a letter outlining the patient safety implications of using EndoWrists beyond their usage limits. In the letter, Intuitive explained that extended instrument usage can impact performance and patient safety. EndoWrists were tested and designed to meet targeted safety and performance specifications. Further, regulatory authorities cleared EndoWrists for use according to those specifications. Finally, the letter informed the customer that the use of remanufactured instruments is a material breach of their contract with Intuitive. Attached to my declaration as **Exhibit 2** is a true and correct copy of an example of such a communication (Intuitive-00980925), a letter Intuitive sent to St. Vincent's Hospital. As far as I have been able to determine, no such communication was ever sent to Franciscan Alliance, King County Public Hospital District No. 1, DBA Valley Medical Center, or Larkin Community Hospital.

V. Iconocare

44. I understand that, on September 30, 2022, the FDA cleared Iconocare Health's 510(k) application, which permits Iconocare to market a remanufactured S/Si 8mm Monopolar Curved Scissor instrument reset one time with ten additional lives. I am not aware of any other EndoWrists that have been cleared to be remanufactured beyond their use limits.

45. To avoid any possibility of confusion, Intuitive has made clear that use of an FDA-cleared remanufactured EndoWrist does not breach any customer's contract or otherwise subject a customer to adverse action from Intuitive. Below is the statement on our website at https://www.intuitive.com/en-us/products-and-services/da-vinci/instruments reflecting Intuitive's position:

Statement on usage limits and use of remanufactured EndoWrist instruments

> "Patients first" has always been core to our mission. Patient safety, product efficacy, and delivering improvements in clinical outcomes guide the design, testing and manufacture of our surgical systems, instruments and accessories.

> With these objectives in mind, we have designed and rigorously tested and validated our EndoWrist instruments with usage and reprocessing limits intended to provide consistent product performance from the first use to the last.
>
> We are aware that certain third parties have sought to offer products or services to healthcare providers that would modify some of our instruments to extend their use. It is our understanding that such modifications constitute remanufacturing under FDA regulations and require 510(k) clearance from FDA.
>
> We recognize the role that third-party medical device servicers have come to play in the medical device ecosystem, and we support healthy, lawful competition in the marketplace. We also have a responsibility to protect patient safety and provide customers with proven, safe and effective tools and technologies. The remanufacturing of EndoWrists is performed by third parties that are not affiliated with Intuitive, and we are not privy to their testing protocols, verifications and validations, remanufacturing processes, or quality controls, among other things. Therefore, Intuitive will not bear responsibility for instruments that are remanufactured by a third party, or for harms or damages caused by the use of such instruments.
>
> However, Intuitive will not void its service contract with, cease doing business with, or consider it a breach of contract by a customer in the United States who chooses to purchase remanufactured instruments that have been remanufactured by a third party pursuant to and in compliance with a 510(k) clearance or equivalent granted by the FDA.
>
> As of March 1, 2023, Intuitive is not aware that FDA has granted 510(k) or equivalent clearance to any party to remanufacture any instruments for use with 4th generation da Vinci technology, including the da Vinci X, Xi and SP systems. Outside of the US, Intuitive is also not aware that any regulatory bodies have granted clearance to any party to remanufacture any instruments for da Vinci systems. For more information about 510(k) clearances granted by FDA, please refer to FDA's publicly available searchable database.

46. This statement accurately reflects Intuitive's current policy towards the activities of EndoWrist remanufacturers. To be clear, Intuitive views tampering with an EndoWrist to reset its use counter through any means ***not*** cleared by FDA as unlawful and potentially dangerous.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: April 12, 2023

David Rosa